

True translation of PCT/EP2003/011869 as filed on October 25, 2003

1703 1362US

Disposable Clothing

Description

The invention concerns a disposable piece of clothing, in particular, for medical, chemical or biochemical use to provide protection against liquids and/or microorganisms, comprising a front part and sleeves which are integrally connected thereto. The piece of clothing may moreover comprise a back part and have, in particular, the shape of a coat. Clothing of this type may be made from an air-permeable non-woven material, wherein reinforcements may be provided in some regions to further improve the barrier that stops penetration of liquids and microorganisms.

EP 0 560 376 B1 describes e.g. a piece of clothing with an outer layer of a densely woven hydrophobic fabric forming a liquid and microorganism barrier and a carrier material with a net-like structure having openings or open meshes, wherein a diaphragm is provided as third layer on this carrier material at critical locations with regard to penetration of liquid or microorganisms.

EP 0 797 505 B1 discloses a piece of clothing with mounted barrier layer, wherein the barrier layer arrangement is thereby applied onto the material substrate as a thin, flexible polymer layer in an additional processing step. The barrier layer sheet is applied from the outer side.

US-A-4,504,977 describes use of hydrophobic and water-impermeable barriers in connection with clothing fabric, in particular, for surgical coats to prevent penetration of water or aqueous solutions. It proposes use of

a coat comprising a layer of hydrophobic non-woven fabric with air voids which consists of micro-fine hydrophobic fibers. Clothes of this type which are preferably worn by persons who work in the medical or chemical field, must provide high comfort during wear even over longer periods and also form a safe barrier against substances, e.g. liquids and microorganisms, in particular, bacteria. In critical areas which are subject to great wear and to intensive substance exposure, e.g. which come in contact with the patient's blood, the substances may penetrate through the clothing. For this reason, a water-impermeable sheet is provided in the breast region that is completely impermeable to water vapour.

Further surgical coats with reinforced regions are disclosed e.g. in US patents 3,868,728 and 5,813,052, the former disclosing a disposable coat and the later a reusable surgical coat.

In view of the above, it is the object of the invention to provide an improved piece of clothing for medical, chemical or biotechnological use which safely prevents penetration of liquid or bacteria for a predetermined time period and at the same time provides good comfort due to its low intrinsic weight and comfortable wearing properties, in particular, during relatively long wear under difficult conditions, e.g. for surgical operating staff.

This object is achieved by a disposable piece of clothing, in particular, for medical, chemical or biotechnological use, as a protection against liquids or microorganisms, comprising a front part and integrally connected sleeves, wherein the piece of clothing comprises an air-permeable outer non-woven layer and wherein at least regions of the side of the outer non-woven material facing the person wearing it, have an air-permeable and liquid-impermeable barrier layer which is connected, at least in sections to the outer layer, and wherein the outer layer is a laminated

material consisting of spunbond and meltblown layers. Laminated material thereby means a layered composite material in the broadest sense. It may be formed through connecting two pre-fabricated layers and also e.g. through integral production of the layered composite material e.g. such that one layer is generated directly through disposing previously produced fibers onto the further layer.

The barrier layer provides, in a straightforward fashion, liquid impermeability which cannot be obtained with conventional non-woven materials, while maintaining air permeability.

In this manner, a particularly light material is moreover produced such that an operating coat of this type is especially comfortable to wear.

With particular advantage, the non-woven material is a spunbond/meltblown/spunbond (SMS) or spunbond/meltblown material (SM) or also an SMMS material. Laminated materials of this type, in particular, of polypropylene are advantageous in that they are particularly soft. All three layers of an SMS laminated material preferably consist e.g. substantially of polypropylene. Further auxiliary substances such as e.g. antioxidants may be provided. The layers permit passage of air, water vapour and heat, while obstructing passage of germs and liquids. Other spunbond-meltblown laminated materials than those mentioned above can also be used.

Laminated materials of this type moreover form only small amounts of fluff, despite their soft surface. The meltblown layer of microfibers thereby form a selective barrier. Moreover, laminated materials of this type have good tearing strength.

A non-woven sheet laminated material may be provided for the barrier layer, wherein the sheet may be a polyethylene sheet filled, in particular, with calcium carbonate or other organic and/or inorganic fillers to form micropores and to provide air permeability in sheets which are usually not air-permeable, while maintaining the liquid and contamination barrier. The sheet may additionally be mechanically finished, in particular, be drawn or rolled to generate porosity.

The barrier layer may preferably be connected to the non-woven material, in particular, in a material-bonding manner, i.e. via glue or welding connections, such as thermal welding or ultrasound welding. The connection between the two materials does not thereby impair the density or the wearing comfort, which could be the case with seamed connections via sewing or through use of buckles or eyelets. If non-woven sheet, laminated materials are used as a barrier layer, the barrier layer may be a sheet mounted between the spunbond-meltblown laminated material and the outer non-woven material of the non-woven laminated sheet such that the non-woven material of the barrier layer, having the comfortable tactile properties, faces the person wearing the piece of clothing.

Barrier layer reinforcement may thereby be provided in the region of the sleeves, in particular, of the lower sleeve ends in the region of the hands to beyond the elbows and/or in the region of the breast, wherein the barrier layer may extend in the breast region to beyond the knee of the person wearing the piece of clothing, in particular, if he/she is standing and/or sitting. Contamination in these areas, which are subjected to the highest contamination exposures, is thereby safely prevented, while further increasing the wearing comfort in the other regions. The sleeves generally have knitted bands at the ends facing the hands, which are overlapped by gloves when used as operating coat and also for chemical

and biotechnological applications. The bands are designed such that they closely fit the arm to prevent sliding and exposure of the skin located between the gloves and the sleeves.

In addition to the above-described embodiment, according to which the outer layer of the entire coat comprises a non-woven material, in particular, a non-woven laminated material of spunbond and meltblown layers, in an alternative design, regions of the clothing may have a non-woven material of spunbond and meltblown layers as an outer layer and regions, in particular, in the region of the sleeves have an outer layer which is formed e.g. by a non-woven sheet laminated material. In addition to non-woven sheet laminated material, materials other than a non-woven material which consists of spunbond and meltblown layers are also feasible. The outer barrier layer in the region of the non-woven sheet laminated material may then be omitted.

In this case, a non-woven sheet laminated material is provided with particular preference in the region of the sleeves, which has a non-woven material component made from spunbond and meltblown layers. To ensure air permeability, the sheet component of this non-woven sheet laminated material may be a sheet which is filled with organic and/or inorganic fillers, providing it with micropores. This non-woven sheet laminated material comprises with particular preference a spunbond/meltblown/spunbond (SMS) or a spunbond/meltblown (SM) or a spunbond/meltblown/meltblown/spunbond (SMMS) laminated material as the non-woven component. The non-woven sheet laminated material may thereby be used such that the non-woven component is disposed on the side facing away from the person wearing the piece of clothing.

The outer layer in a region of the coat, in particular, in the region of the sleeves may alternatively be a non-woven sheet laminated material

which is formed from several non-woven material components and a sheet component. A non-woven sheet laminated material of this type preferably comprises two non-woven components and a sheet. The non-woven components preferably comprise a non-woven material which consists of a laminated material comprising spunbond and meltblown layers. In a particularly preferred manner, this non-woven sheet laminated material comprises a spunbond/meltblown/spunbond (SMS) or a spunbond/meltblown (SM) or a spunbond/meltblown/meltblown/spunbond (SMMS) laminated material as non-woven component. The non-woven sheet laminated material may be formed in particular symmetrically with respect to the central layer. This means, in particular, the sheet may be the central layer, wherein the non-woven component is identically provided mirror-symmetrically on both sides of the sheet.

The use of such non-woven sheet laminated material, in particular, in the region of the sleeves is advantageous since the production of the sleeves is particularly complex, and moreover material is reduced, in particular, in the region of the overlappings between sleeve seams or welding points. At the same time, a certain barrier effect can be obtained.

Moreover, an associated piece of clothing can have a back part and be designed, in particular, as a wrap-around or closed coat. The wrap-around coat overlaps in the back such that the coat does not easily open and at the same time is easy to put on, while maintaining a sterile state. The coat may also be designed as a closed coat which is preferably used for short operations with little amounts of liquid involved and small infection risk. Further disposable operating clothes can also be designed in this manner. The outer non-woven material or another material used in some regions, can be welded to prevent passage of liquid and bacteria through seams. The additional reinforcing material, in particular, in the

sleeves may initially be connected to the non-woven material and the sleeve is brought into its final tubular shape through welding.

The seams, in particular, on the sleeves may be folded-over or overlapping seams or combinations thereof to further improve protection against entering liquid. The seams may additionally be closed by an additional sheathing. Seams of this type are disclosed e.g. in EP 560 376 B1.

The piece of clothing may be conventionally folded when not in use to ensure sterile application.

The clothing should have a penetration resistance to water at the reinforced locations of $\geq 150\text{cm}$ (measured according to EN 20 811) and, in particular of $\geq 200\text{ cm}$.

The surface density should preferably be $\leq 90\text{g/m}^2$ and, in particular $\leq 80\text{g/m}^2$ in the combined layers.

The water vapor permeability at the reinforced locations should finally be preferably $\geq 2000\text{ g/m}^2$ (measured according to DIN 53 122-1 (climate B)). Penetration of ethanol shall be prevented to at least 80% (corresponding to the test described below) and, in particular, to at least 96%.

A piece of clothing of this type should, in particular, have a high penetration resistance to water which is exemplarily explained by a comparison of SMS material, non-woven sheet laminated material, and both laminated materials together and, in particular, a material as used in the Ultra operating coat of the Kimberly Clark firm. It consists of two

layers of a special SMS material at the reinforced locations as outer material and as barrier layer.

A simple SMS non-woven material has a surface density of approximately 35g/m^2 . The non-woven material consists of 100% polypropylene. The non-woven sheet laminated material used comprises a sheet which consists of polyethylene and calcium carbonate as filler and has a surface density of approximately 38 g/m^2 .

In contrast thereto, the double-layered material of Kimberly Clark has a surface density of 52 g/m^2 per layer.

The water penetration resistance of the individual materials and of the inventive combination was determined according to the EN 20 811 standard. The non-woven material alone only had a small resistance of 36 cm. The resistance of the non-woven sheet material was 216 cm. The combined material of outer layer and barrier layer can therefore provide a water penetration resistance of 233 cm.

The Kimberly Clark material tested in comparison thereto, has showed a value of approximately 133 cm.

A water vapor permeability test measured according to DIN 53 122-1 (climate B) showed a water vapor permeability of $6,656\text{ g/m}^2$ in 24 h for the outer non-woven material alone. The barrier layer obtained a value of $3,217\text{ g/m}^2$ in 24 h which results in a water vapor permeability of $2,341\text{ g/m}^2$ in 24 h for the overall material consisting of the outer non-woven material and the barrier layer. The material of the Kimberly Clark coat showed a permeability of $6,394\text{ g/m}^2$ which corresponds substantially to the permeability of the outer material of the inventive clothing.

The inventive clothing also has very good alcohol repelling properties which can be determined using the standard test IND A Ist 80.9-74 (R77) and also by the following further testing method:

Testing method for alcohol repelling properties of non-woven materials:

Test devices: pipettes
 Transparent glass or plastic plate
 Mirror
 Lamp

Reagents: The test liquids were prepared according to table 1 and numbered consecutively.

Table

Test solution (mixing ratio (%))	evaluation grade
Ethanol/demin. H ₂ O)	

Ethanol 96% *	demin. H ₂ O **	
0	100	0
10	90	1
20	80	2
30	70	3
40	60	4
50	50	5
60	40	6
70	30	7
80	20	8
90	10	9
100	0	10

* ...denaturated ethanol 96%

** ..demineralized water

Sample preparation:

At least 2 specimens (approximately 200 x 200 mm) are required. They are stored in a climatic chamber for 4 h at a temperature of $20 \pm 2^{\circ}\text{C}$ and at a relative air humidity of $65 \pm 2\%$.

The test sample is flatly disposed onto a smooth horizontal glass or plastic plate.

The test is started with the test liquid with the lowest number (alcohol repelling grade 0). A small drop (of a diameter of approximately 5mm) is disposed onto the test sample at at least three locations using the pipette. After 5 minutes, it is checked whether or not the test liquid has penetrated into the test sample. If no penetration occurred within these 5 minutes, drops of the test liquid with the next higher number are disposed at a bordering location onto the test sample which is again observed after 5 minutes.

The test is continued until one of the test liquids penetrates through the test sample.

Two or more drops of the test liquid are simultaneously applied onto the specimen.

Analysis:

The alcohol repelling grade of the non-woven material is the number of the test liquid with the highest number which has not penetrated through the non-woven material after 5 minutes.

Normally that penetration is decisive which shows complete or partial darkening of the non-woven material directly below the test liquid, viewed from the rear side. The final point can often be determined by turning the test sample after the 5 minute interval.

Reference to standards: INDA standard test
 IST 80.9 - 74 (R77)

The simple non-woven material did not show any penetration up to 80% alcohol. The non-woven sheet material and the laminated material of non-woven sheet and outer non-woven material showed no alcohol penetration up to 96%. The double SMS material of Kimberly Clark also showed no alcohol penetration up to 96%.

Finally, tests with blood salt solutions were carried out, the so-called Coverstock Wetback test following the EDANA standard 151.0-93 with the following changes, i.e. use of a blood substitute solution instead of the salt solution, with the following recipe:

- 1) 100g glycerol 85%
 100 g distilled water
 1.8 g sodium chloride
 0.1 g Congo Red.
- 2) blood substitute solution according to 1) + 5 g/l butter.

The base was a glass plate and the test was carried out as follows:

A soaking body (filter paper) is soaked with 40 g blood substitute solution according to 1 or 2. The dwell time is two minutes. The specimen, either the non-woven material, the sheet material or the combined material is disposed with its outer side onto the soaking body. A filter paper is subsequently disposed onto the specimen onto which a PE foam rubber support is disposed. The specimen is loaded with 4,000 g for 3 minutes. The filter paper is subsequently re-weighed.

The first mentioned blood substitute solution achieved a value of less than 5g for the outer non-woven material alone. The blood substitute solution + 5 g/l butter obtained a value less than 10. The barrier layer material and also the non-woven material including the barrier material showed a penetration of 0 g each. These materials are therefore highly repellent, in particular, for blood. 0.04 g of the blood substitute solution and 0.02 g of the blood substitute solution with butter penetrated through the double SMS non-woven material of Kimberly Clark.

The invention is explained in more detail below with reference to the drawing.

Fig. 1 shows an inventive piece of clothing;

Fig. 2 shows a section through a piece of clothing according to Fig. 1 in the region of a reinforced zone.

A piece of clothing, e.g. an operating coat 10 comprising an outer material 12 which forms the clothing 10 of a three-layered polypropylene non-woven material of SMS material with a meltblown central layer of microfibers in the form of the wrap-around coat shown, presents a safe and comfortable protective piece of clothing for operations involving large

amounts of liquids and high risk of infection. The outer material 12 has good resistance to penetrating moisture and germs, is wear-resistant, and produces nearly no fluff.

The sleeve seams (not shown) may, in particular, be provided on the upper side of the sleeves, and elastic protective bands 14 of 100% PES are disposed at the end 16 of the sleeves. The sleeves 20 are Raglan sleeves which provide more freedom of movement.

A coat 10 of this type can be closed in the region of the neck 18 using a Velcro fastener disposed in the back region. In case of a wrap-around coat 10, the back part has a particularly wide overlapping to obtain two back parts. The first and second back parts may be fastened via tied straps to securely fix the overlapped portion.

The lower arm 22 region and the breast and leg regions 24 may have additional liquid-repellent, but air-permeable reinforcements provided by a barrier layer of a non-woven sheet laminated material. The laminated materials provided in the reinforcing region may be laminated material connected by fusion adhesive, of polypropylene spun non-woven material and stretched polyethylene/calcium carbonate sheet. The lower arm reinforcement 22 and the non-woven material are sewn at the bottom to the arm band 14 and welded to the outer non-woven material 12 in the upper region, i.e. the elbow region 26.

The breast reinforcement 24 may be fastened to the upper 12, non-woven material of the coat 10 at individual, in particular, seven locations (e.g. three at the top, two at the bottom and two on the side). The reinforcement 24 in the breast region may have a trapezoidal shape and be sufficiently long to also protect the hips and legs of the person wearing it.

Fig. 2 shows a section through a piece of clothing in accordance with Fig. 1 in the region of the provided reinforcements, e.g. in the breast region 24. Only a section of the inventive piece of clothing is shown. The outer material 12 thereby has a three-layered structure with two outer layers 12' and 12'', wherein the layer 12' forms the outside of the coat and wherein these two layers are made from a spunbond material as described above, having a surface density of approximately 13 g/m^2 . The central layer 12''' consists of a meltblown material with a surface density of approximately 9 g/m^2 which forms a first barrier for liquids and bacteria. The layers 12' and 12'' have soft and fleecy visual and haptic properties and provide comfortable wear of a piece of clothing 10 of this type on the inside and outside. The breast region 24 inner side i.e. the side 28 facing the person wearing it, has an additional reinforcement of the non-woven sheet laminated material, which is a laminated material connected through fusion adhesive with a polypropylene spun non-woven material 13' having a surface density of approximately 18 g/m^2 and a polyethylene sheet 13'' which is filled with a filler, i.e. calcium carbonate to generate the microporosity, wherein the entire sheet has a surface density of approximately 18 g/m^2 . The fusion adhesive connecting the two layers is applied with 2 g/m^2 . The sheet is additionally mechanically finished, in particular, through stretching to obtain good air permeability. The non-woven sheet laminated material 13 of the barrier layer is thereby connected to the outer non-woven material 12 e.g. through thermal welding connections or ultrasound welding. The barrier layer is liquid-proof and also bacteria-proof, but permits passage of heat and water vapor to ensure comfortable wear of the piece of clothing.

Further advantages and features can be extracted from the remaining application documents which are essential to the invention individually and in arbitrary combination.